

REMARKS

Claims 1-7 and 10-21 are pending in the present application.

The rejections of Claims 1-5 under 35 U.S.C. §102(b) over Hurnaus et al or Shuker et al as supplemented by Greene is obviated by amendment.

In the amendment herein above, Applicants have amended Claim 1 to include the following specific proviso:

- and further with the proviso that said compound of salt thereof meets one of the following conditions:
- at least one of R⁵ and R⁸ is selected from the group consisting of halogen, hydroxy, lower alkyl having 2-6 carbon atoms, lower alkenyl, lower alkoxy, hydroxy(lower)alkoxy, mono-halo(lower)alkoxy, di-halo(lower)alkoxy, tri-halo(lower)alkoxy, lower alkoxy(lower)alkoxy, lower alkenyloxy, cyclo(lower)alkyloxy, cyclo(lower)alkyl(lower)alkoxy, benzyloxy, phenoxy, lower alkylthio, cyclo(lower)alkylthio, lower alkylsulfonyl, cyclo(lower)alkylsulfonyl, amino, mono-(lower)alkylamino, di-(lower)alkylamino, mono-halo(lower)alkyl, di-halo(lower)alkyl, tri-halo(lower)alkyl, cyano, piperidinyl and phenyl;
 - both R⁵ and R⁸ are a lower alkyl; or
 - when Y is a bond and R⁵ and R⁸ are both hydrogen, Z is selected from the group consisting of cyano, tetrazolyl, (benzylsulfonyl)carbamoyl, benzoylsulfamoyl, and formyl.

Applicants note that this proviso, which is fully supported by Claims 1-5 as originally presented, distinguishes the present invention from the compounds disclosed by Hurnaus et al and Shuker et al. The closest compounds disclosed in these references to the presently claimed invention is that in Example 6 of Hurnaus et al and CA 127:277798 disclosed by Shuker et al. However, structural comparison of these compounds to the aforementioned proviso will evidence the fact that these prior art compounds fall outside the scope of the presently claimed invention.

Specifically, CA 127:277798 disclosed by Shuker et al cannot fall within the scope of the presently claimed invention for the following reason:

First proviso: CA 127:277798 disclosed by Shuker et al has both R⁵ and R⁸ as hydrogen, thus falling within the scope of this proviso;
Second proviso: CA 127:277798 disclosed by Shuker et al has both R⁵ and R⁸ as hydrogen, thus falling within the scope of this proviso; and
Third proviso: CA 127:277798 disclosed by Shuker et al has both R⁵ and R⁸ as hydrogen and Y as a bond; however, Z in this compound is an amine protected carboxy which falls outside the scope of this proviso.

In regard to the compound of Example 6 of Hurnaus et al, as well as the generic phenylethanolamine structure defined therein, these compounds cannot fall within the scope of the presently claimed invention for the following reason:

First proviso: the genus of compounds disclosed by Hurnaus et al, including that of Example 6, have both R⁵ and R⁸ as hydrogen, thus falling within the scope of this proviso;
Second proviso: the genus of compounds disclosed by Hurnaus et al, including that of Example 6, have both R⁵ and R⁸ as hydrogen, thus falling within the scope of this proviso; and
Third proviso: the genus of compounds disclosed by Hurnaus et al, including that of Example 6, have both R⁵ and R⁸ as hydrogen and Y as a bond; however, the substituent corresponding to Z is not included in the list of alternatives recited in the present claims and, thus, this disclosure falls outside the scope of this proviso.

In view of the fact that neither Hurnaus et al nor Shuker et al disclose a compound within the scope of present Claim 1, Applicants submit that these references cannot anticipate the claimed invention.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 1-5 under 35 U.S.C. §103(a) over Hurnaus et al is obviated by amendment.

This ground of rejection is based on the Examiner's inference that it would be obvious to modify the compound disclosed by Hurnaus et al (RN 121805-22-9) by replacing a

hydrogen atom at R⁵ or R⁸ with a methyl group. Applicants note the claims (in particular the first proviso added to Claim 1) no longer permit for a single substitution of one of R⁵ or R⁸ with a methyl group, which the Examiner deems obvious *per se*.

Moreover, the Examiner is reminded that homology and isomerism involve close structural similarity, which must be considered with all other relevant facts in determining the issue of obviousness. *In re Mills*, 281 F.2d 218, 126 USPQ 513 (CCPA 1960); *In re Wiechert*, 370 F.2d 927, 152 USPQ 247 (CCPA 1967). Therefore, homology should not be automatically equated with *prima facie* obviousness because the claimed invention and the prior art must each be viewed "as a whole." *In re Langer*, 465 F.2d 896, 175 USPQ 169 (CCPA 1972). In the present application, this would mean that the relevant question to ask would be whether the skilled artisan would envision the claimed class of compound where Hurnaus et al is silent. More specifically, where each and every compound disclosed by Hurnaus et al *requires* the presence of a hydrogen atom at both R⁵ and R⁸, where would the skilled artisan find motivation to substitute one of these for a lower alkyl having 2-6 carbon atoms (i.e., the closest point of contact between Hurnaus et al and Claim 1 (first proviso)) absent Applicants disclosure?

In view of the foregoing and the amendments herein, Applicants submit that the present invention is not obvious in view of the disclosure of Hurnaus et al. Withdrawal of this ground of rejection is requested.

The rejection of Claims 7 and 11 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Consistent with the Examiner's suggestion, Claim 7 has been amended to remove "as an active ingredient" and to insert "therapeutically effective amount." Also consistent with

the Examiner's suggestion, Claim 11 has been amended to define the human or animal as being "in need" of treatment. In addition, Claim 11 has been amended to remove the confusing language of "prophylactic and/or the therapeutic treatment" and to define the amount of the compound added as being a "therapeutically effective amount."

In view of these amendments, Applicants submit that Claims 7 and 11 are definite and request withdrawal of this ground of rejection.

The objection to Claims 9 and 10 under 37 C.F.R. §1.75 as being a substantial duplicate of Claim 1 is obviated by amendment.

Applicants note that in the amendment herein, Claim 9 have been canceled and Claim 10 has been rewritten to be a method claim. Therefore, this ground of objection is believed to be moot.

Applicants request acknowledgment that this ground of objection has been withdrawn.

Finally, Applicants remind the Examiner that MPEP §821.04 states:


...if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim *will* be rejoined. (*emphasis added*)

Upon a finding of allowability of the elected product claims, Applicants respectfully request rejoinder of the withdrawn process claims.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)